DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

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WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 14, 1996

Seymour Budoff, President
Gemini Pharmaceuticals, Inc.
81 Keyland Court
Bohemia, New York 11716

re: 16-NYK-97

Dear Mr. Budoff:

We have completed our review of your August 19, 1996 and October 2, 1996 letters, responding to observations made by our investigator during the inspection of your facility August 7 to August 15, 1996. Our review has concluded your response is inadequate. We are advising you that the observations constitute significant deviations from the Current Good Manufacturing Practice Regulations for the manufacturing, processing, packing, or holding of drugs (Title 21, Code of Federal Regulations, Parts 210 and 211). These deviations cause the drug products Acetaminophen 500 mg tablets, Guaifenesin and Ephedrine Hydrochloride 100mg/25 mg tablets, Pseudoephedrine Hydrochloride 60 mg tablets, and Caffeine 125 mg tablets manufactured by your firm to be adulterated within the meaning of section 501(a)(2)(B) of the Food, Drug and Cosmetic Act (the Act). The deviations are as follows:

1. Failure to have adequate written procedures establishing criteria for the release or approval of drug component ingredients. There is lacking an adequate program to qualify the supplier and establish the specifications of the ingredients. There is lacking an adequate program to establish and perform procedures for the acceptance of individual shipments of drug component ingredients.

2. Failure to establish and follow adequate controls to monitor and validate manufacturing processes that may be responsible for causing variability in in-process materials and the drug product. The data you submitted in your response letters fails to include in process testing, including, but not limited to, testing to assure adequacy of mixing and testing to assure adequacy of the compression process.

The above cited violations should not be regarded as all inclusive It is your responsibility to ensure that all requirements of th Federal Food Drug and Cosmetic Act and all regulations promulgate thereunder, are being satisfied for all products subject to thes requirements.

We request that you take prompt action to correct these deviations Federal agencies are advised of the issuance of all Warning Letter about drugs so that they may take this information into accoun when considering the award of contracts. Failure to promptl correct these deviations may result in regulatory action withou further notice, such as seizure or injunction.

You should notify this office in writing, within 15 working days o receipt of this letter, of the status of the specific steps yo have taken or intend to take to correct the noted violations Include an explanation of each step being taken to prevent th recurrence of similar violations and a timetable for correction.

Your reply should be sent to the Food and Drug Administration, Ne York District Office, at the above address, Attention: Willia Friedrich, Compliance Officer.

Sincerely,

Lillian Aveta
Acting District Director
New York District